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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,197	09/27/2005	Funda Elger	K21722USWO (C038435/01913)	4609
7590 Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104	02/03/2010		EXAMINER GREENE, IVAN A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/551,197	ELGER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	IVAN GREENE	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 November 2009.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5, 7-9 and 11-23 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-5, 7-9 and 11-23 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/27/2009</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Status of the claims***

Claims 1-5, 7-9 and 11-23 are currently pending and are presented for examination on the merits. Claims 6 and 10 have been canceled by applicant. Claims 18-23 are new.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/27/2009 has been entered.

All rejections and/or objections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

The information disclosure statement(s) submitted on 11/27/2009 was filed before the mailing of a first office action after the filing of a request for continued examination under. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

The U.S. effective filing date has been determined to be 03/24/2004, the filing date of the document PCT/EP04/03110.

***Claim Rejections - 112 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Claims 7 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.**

Claims 7 and 21 have been amended to include the limitation --the fat soluble active ingredient is present in a plant or animal oil or fat-- there is no support for this limitation in the specification as originally filed. The examiner cannot find support for the limitation that the "fat soluble active ingredient is present in a plant or animal oil or fat" in the specification at paragraph [0008] (as published) or in claims 6 or 7 as originally filed, as indicated by applicant in the reply dated 11/27/2009. Applicant should amend the claim to remove the new matter or specifically point out the reasoning used for support of this amendment.

***Claim Rejections - 112 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. **Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**
2. Claims 2-4 are rejected as being indefinite because the claims recite --the lupin protein-- and each depend from claim 1 which recites the narrower limitation --a native lupin protein--. It is unclear what type of lupin protein is required by claims 2-4.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. **Claims 1-5, 7-9, 15 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636) in view of JONES (US 2002/0187185) and FITCHETT (WO 1999/11143).**

***Applicants claim***

Applicant claims a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked and the fat-soluble active ingredient is selected from the group consisting of vitamin A, vitamin D, vitamin E, vitamin K, a carotenoid, a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing. Applicant further claims the formulation wherein the native lupin protein is an isolate (protein content of greater than 90 wt. %), a concentrate (protein content of 60-90 wt. %), or a flour (protein content of 40-60 wt. %). Applicant further claims the formulation comprises a reducing sugar selected from glucose, fructose, or xylose; and the reducing sugar is cross-linked with the protein matrix. Applicant further claims a food, beverage, animal feed, cosmetic, or drug comprising the stable powderous formulation.

**Determination of the scope and content**

**of the prior art (MPEP 2141.01)**

SCHNEIDER teaches a process for preparing stable dry powders which are insoluble in hot water and which contain fat-soluble vitamins and/or carotenoids comprising preparing an aqueous emulsion of the fat-soluble active ingredient, a film-forming colloid (gelatin) and a reducing sugar, converting the emulsion into a dry powder and submitting the dry powder to cross-linking of the proteins by heat treatment (abstract).

SCHNEIDER further teaches, "The fat-soluble vitamins include vitamins A, E, D and K as well as mixtures thereof. For the purpose of the present invention they can be

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employed in the form of vitamin solutions in oils...Particularly interesting products contain vitamin A and its derivatives, especially vitamin A acetate, vitamin A palmitate..." (3:59-66). SCHNEIDER further teaches the sugars can be any reducing sugars or syrup containing reducing sugars including fructose, glucose, lactose, maltose, xylose, arabinose, ribose and invert sugar (4:11-17). SCHNEIDER further teaches, "In addition to the obligatory ingredients, it is advantageous to add to the dispersion other compounds customary in the preparation of active substance dry powders" (4:59-63). SCHNEIDER goes on to teach the additives starch, maltodextrin, alginates (5:8-9) and hydrophobic silica (4:42).

JONES teaches a gelatin substitute (title) of vegetable origin suitable [for use] in capsule or microcapsule manufacture (abstract). JONES further teaches their invention relates to new vegetable derived protein materials which have good physical properties and may be used to replace gelatin in a diverse range of applications, especially in pharmaceutical capsule manufacture ([0001]). JONES further teaches commercial uses for gelatin have been established in a wide range of industries, including applications in food, pharmaceutical, medicinal, photographic, cosmetic and technical products ([0003]). JONES further teaches gelatin is also used for the microencapsulation of oils and vitamins (especially vitamins A and E) for edible and pharmaceutical uses ([0003]). JONES further teaches microcapsules comprising oils are normally in the form of a granular powder [...] and are formed by first emulsifying the oil phase in gelatin solution then spray-drying or spray-chilling the emulsion ([0005]). JONES further teaches the

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ability of gelatin to stabili[z]e the emulsion is an important feature [and] the gelatin may be extended by the inclusion of sugars [...] to lower the cost of production ([0005]).

JONES teaches:

**[0006]** Despite the outstanding properties exhibited by gelatin, alternatives to gelatin are currently being sought, particularly in the pharmaceutical industry. This is partly due to religious and vegetarian pressures, which have created a desire to move to non-animal based products. Unsubstantiated concerns over gelatin presenting a potential risk from BSE (bovine spongiform encephalopathy) have also fuelled interest in alternatives.

JONES teaches their invention overcomes many of the disadvantages of the current gelatin alternatives for encapsulating applications by using high molecular weight, water-soluble proteins, derived from vegetable sources ([0016]). JONES further teaches the high-molecular weight soluble proteins may be produced by a combination of hydrolysis and cross-linking reactions [...by, for example...] heat treatment of dry protein ([0040] & [0041]). JONES further teaches the preferred protein starting materials are 'isolates', since they contain the highest protein content, however, protein 'concentrates' and protein meals can also be used ([0042]). JONES further teaches the examples of suitable vegetable-derived protein raw materials include lupin, inter alia ([0044], [0057] and claim 15).

**Ascertainment of the difference between the  
prior art and the claims (MPEP 2141.02)**

The difference between the rejected claims and the teachings of SCHNEIDER

and JONES is that SCHNEIDER and Jones do not expressly teach a native lupin protein; or the lupin protein isolate concentrations. The deficiencies in the native lupin protein and the lupin protein isolate concentrations are cured by FITCHETT.

FITCHETT teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) are widely used in the food industry (pg. 1, lines 9-15). FITCHETT further teaches "Lupins have long been recognized as a viable alternative to soya as a source of vegetable protein for human consumption" (pg. 2, line 7). FITCHETT further teaches "It has long been known that the protein content of lupin seeds is equal to that of whole soya beans, and it has been exploited for years as a sources of (non-functional) protein in animal feeds" (pg. 2, lines 12-14). FITCHETT further teaches, the lupin protein is preferably present in substantially native form which is associated with higher functionality (pg. 4, lines 10-12).

### **Finding of *prima facie* obviousness**

#### **Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of JONES and FITCHETT with SCHNEIDER because SCHNEIDER teaches a stable dry powder comprising a fat-soluble active substance encapsulated in a cross-linked gelatin protein, JONES teaches a gelatin protein substitute lupin and FITCHETT teaches lupin protein compositions. A person having ordinary skill in the art would have been motivated to use the protein gelatin substitute, lupin protein taught by JONES and FITCHETT, in the

invention of SCHNEIDER because, as taught by JONES, alternatives to gelatin are being sought because of the consumer desire to have vegetable-based alternatives to animal-based gelatin.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

**2. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636) in view of JONES (US 2002/0187185) and FITCHETT (WO 1999/11143), as applied to claims 1-5, 7-9, 15 and 18-23 above, and further in view of TASHIRO (US 4,855,157), and as evidenced by the Merck Index (entries for "Sunflower Seed Oil," "corn oil" and "Oil Palm").**

***Applicants claim***

Applicant claims a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein, as discussed above. Applicant further claims the stable powderous formulation wherein the plant oil is selected from the group consisting of sunflower oil, palm oil and corn oil.

SCHNEIDER teaches a stable dry powders which contain fat-soluble vitamins and/or carotenoids, which are prepared as using the film-forming colloid gelatin, as discussed above.

JONES teaches a gelatin substitute (title) of vegetable origin suitable [for use] in capsule or microcapsule manufacture; the microencapsulation of oils and vitamins (especially vitamins A and E) for edible and pharmaceutical use; and the example of a suitable vegetable-derived protein raw material lupin, as discussed above.

FITCHETT teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) are widely used in the food industry; and the lupin protein is preferably present in substantially native form which is associated with higher functionality, as discussed above.

SCHNEIDER and JONES do not teach the oil species sunflower oil, palm oil or corn oil. This deficiency in the oil species is cured by the teachings of TASHIRO as evidenced by the Merck Index.

TASHIRO teaches two known process for producing a fat containing powder include, first spray-drying a fat or oil which has been emulsified into an oil-in-water type emulsion, and second atomizing a molten fat or oil in an atmosphere at a temperature that is lower than the melting point of the fat or oil (1:9-19). TASHIRO further teaches sunflower oil, corn oil, and palm oil, inter alia (2:27).

The Merck Index teaches sunflower seed oil comprises 66.2% of the polyunsaturated fatty acid linoleic acid and 75mg/100g of Vitamin E. The Merck Index teaches oil palm comprises 10% linoleic acid, carotenoids, and tocopherols (vitamin E).

The Merck Index teaches corn oil comprises 34-62% linoleic acid and  $\gamma$ -tocopherol (vitamin E). Therefore, it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the claimed invention was made that the recited oils (sunflower, corn and palm) comprise vitamins, carotenoids and/or polyunsaturated fatty acids (hereafter VCP) as evidenced by the Merck Index entries for said oils.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of TASHIRO with the teachings of SCHNEIDER because SCHNEIDER teaches products comprising vitamins in oils and TASHIRO teaches the VCP containing oil sunflower oil, corn oil, and palm oil. A person having ordinary skill in the art would have been motivated to combine the VCP containing oil of TASHIRO with the composition because the oils taught by TASHIRO would have been widely available and would provide for a more nutritious and therefore desirable product.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

**3. Claims 11-13, 16 and 17 are rejected under 35 U.S.C. 103(a) as being**

**unpatentable over SCHNEIDER (US 5,356,636) in view of JONES (US 2002/0187185), FITCHETT (WO 1999/11143) and GERRARD (Trends in Food Science and Technology, 13, 2002, pp. 391-399); and as evidenced by SIEPAÍO (Journal of Agricultural and Food Chemistry, 1995, Vol. 43, pp. 1151-1156).**

***Applicants claim***

Applicant claims a process for the preparation of a formulation comprising preparing an aqueous preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition, wherein a reducing sugar is added and the composition is submitted to cross-linking by heating.

Applicant claims a process for the preparation of a formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition, wherein the composition is submitted to cross-linking by treatment with a cross-linking enzyme. Applicant further claims the cross-linking enzyme is transglutaminase.

Applicant claims a process for the preparation of a powderous formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition, adding a reducing sugar, and converting the emulsion into a dry powder. Applicant further claims the process further comprising submitting the dry powder to heat treatment or treatment with a cross-linking enzyme, to cross-link the protein of the dry powder.

**Ascertainment of the difference between  
the prior art and the claims (MPEP 2141.02)**

SCHNEIDER teaches a process for preparing stable dry powders comprising the steps of (a) preparing an aqueous dispersion containing fat-soluble [vitamins or carotenoids], film-forming colloids, and reducing sugars; (b) converting this dispersion into a dry vitamin and/or carotenoids products in powder form; and (c) thermally curing the powder at from 60°C to 180°C (abstract). SCHNEIDER further teaches the thermal treatment of the initially obtained powder results in the gelatin content being denatured owing to reaction of its free amino groups with the reducing sugars (Maillard reaction) (3:34-37). SCHNEIDER further teaches the process according to their invention has the advantage that the customary crosslinking temperatures are reduced in the presence of amino compounds and/or the basic compounds (i.e. crosslinking is possible at 60°C or above) (3:48-53).

JONES teaches a gelatin substitute (title) of vegetable origin suitable [for use] in capsule or microcapsule manufacture; the microencapsulation of oils and vitamins (especially vitamins A and E) for edible and pharmaceutical use; and the example of a suitable vegetable-derived protein raw material lupin, as discussed above. JONES teaches their invention overcomes many of the disadvantages of the current gelatin alternatives for encapsulating applications by using high molecular weight, water-soluble proteins, derived from vegetable sources ([0016]). JONES further teaches the high-molecular weight soluble proteins may be produced by a combination of hydrolysis and cross-linking reactions [and the cross-linking reactions] may include the controlled use of the enzyme transglutaminase, which is capable of forming cross-links between glutamine and lysine residues in the protein chains ([0040]).

FITCHETT teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) are widely used in the food industry; and the lupin protein is preferably present in substantially native form which is associated with higher functionality, as discussed above.

GERRARD teaches methods for protein-protein crosslinking including the use of transglutaminase catalysis (p. 394, lines 27-56, col. 2 lines 1-2). GERRARD further provides the motivation to use enzymes for protein-protein crosslinking (p. 395, col. 1):

### Enzymatic methods

The use of enzymes to modify the functional properties of foods is an area which has attracted considerable interest, since consumers perceive enzymes to be more ‘natural’ than chemicals. Enzymes are also favoured as they require milder conditions, have high specificity, are only required in catalytic quantities, and are less likely to produce toxic products (Singh, 1991). Thus enzymes are becoming commonplace in many industries for improving the functional properties of food proteins (Chobert *et al.*, 1996; Poutanen, 1997).

SIEPAÏO teaches :

(Signorini *et al.*, 1991). In order to diversify the supply of TGase, we have looked for a TGase in white lupine seedlings.

(p. 1151, introduction last line of first paragraph; TGase = transglutaminase). And SIEPAÏO confirmed the presence of transglutaminase in lupine seeds:

tion at 108000g for 1 h (Table 2). This experiment confirmed that the TGase contained in the 41400g pellet either was an integral membrane protein or was bound to the integral membrane protein. The nature of the

(p. 1152, col. 2, last line; and p. 1153, col. 1, lines 1-3).

### **Finding of *prima facie* obviousness**

#### **Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of JONES and FITCHETT with SCHNEIDER because SCHNEIDER teaches a process for preparing stable dry powder comprising a fat-soluble active substance encapsulated in a cross-linked gelatin protein, JONES teaches a gelatin protein substitute lupin and FITCHETT teaches lupin protein compositions. A person having ordinary skill in the art would have been motivated to use the protein gelatin substitute, lupin protein taught by JONES and FITCHETT, in the process of SCHNEIDER because, as taught by JONES, alternatives to gelatin are being sought because of the consumer desire to have vegetable-based alternatives to animal-based gelatin.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of GERRARD with the teachings of SCHNEIDER because SCHNEIDER teaches a process for making a vitamin food product containing crosslinked proteins and GERRARD teaches methods for protein-protein crosslinking useful in food products. A person having ordinary skill in the art would have been motivated to combine GERRARD with SCHNEIDER because

the various different crosslinking methods, as taught by GERRARD, would have provided different routes for achieving the best possible crosslinked protein food product. And consulting the protein-protein crosslinking methods taught by GERRARD would have saved the time and money required to newly discover what is already known. A person having ordinary skill in the art would have been motivated to use the cross-linking enzyme transglutaminase, as taught by JONES, in the invention of SCHNEIDER because, as taught by GERRARD, the consumer would have favored products using enzymes as more natural. A person having ordinary skill in the art would have had a reasonable expectation of success in using transglutaminase to crosslink lupin protein because, as evidenced by SIEPAÍO, native lupin seeds contain the enzyme transglutaminase as an active metabolic enzyme.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

**Response to Arguments:**

Applicant's arguments filed 11/27/2009 have been fully considered but they are not persuasive.

Applicant's arguments against the reference FITCHETT have been considered, however, in view of the new grounds of rejection (wherein FITCHETT is no longer the primary reference), most of applicant's arguments are moot. The arguments that remain relevant are addressed below.

Applicant's argument that there would be no suggestion or motivation to choose native lupin protein [which is taught by FITCHETT] is not convincing because FITCHETT teaches the preferred form of lupin protein is the native form:

As described in more detail below, the lupin protein for use according to the invention may be provided in any suitable form or physical state. Preferably, it is present in substantially native form, since this is usually associated with higher functionality. It is also preferably debittered, for the reasons described in more detail below.

(p. 4, lines 9-12).

Applicant's argument that Gerrard provides no disclosure that the cross-linking can be applied to lupin protein, is not convincing because the reactions taught by Gerrard can be applied to "food protein, either native or denatured" (see p. 392, Figure 1) and the described reactions would clearly apply to lupin food protein. And as evidenced by SIEPAïO, native lupin seeds contain the enzyme transglutaminase as an active metabolic enzyme.

### ***Nonstatutory Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**1. Claims 1, 7-9, 11 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 12-14, 16 and 17 of copending Application No. 10/564,635 (hereafter referred to as '635) in view of PERRIER (US 5,912,016).**

Instant claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix formed from native lupin protein composition wherein the protein in the matrix is cross-linked and the fat-soluble active ingredient is vitamin A, D, E or K, or carotenoids, or a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing; instant claim 11 recites, a process for the preparation of a formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition, wherein a reducing sugar is added and the composition is submitted cross-linking by heating. Instant claim 7 recites the formulation wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Instant claim 8 recites formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Copending '635 claim 14 recites, formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Instant claim 8 is coextensive in scope with copending '635 claim 14. Instant claim 13 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the native lupin protein composition, adding the reducing

sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein by heat treatment or by treatment with a cross-linking enzyme.

Copending '635 claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of milk protein compositions, wherein the protein is thermally cross-linked with a reducing-sugar. Copending '635 claims 6 recites the formulation additionally comprises a plant protein and copending '635 claim 8 recites formulations which further comprise plant protein which is obtained from potato protein, soy protein, wheat protein, pea protein, rice protein or lupin protein. Copending '635 claim 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; copending '635 claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Copending '197 claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein with heat treatment.

The difference between Copending '635 and the instant claimed invention is that copending '635 does not explicitly teach the use of lupin protein for the primary cross-linking protein. The deficiency of using a lupin protein is cured by the teachings of PERRIER, which teaches particles of cross-linked lupin plant proteins wherein the particles encapsulate active substances, including lipophilic active principles, as discussed above.

It would have been *prima facie* obvious to combine copending '635 with the teachings of Perrier et al. and produce the instant claimed invention because both applications teach cross-linked protein food additives with a fat-soluble active ingredient in the protein matrix. It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a cross-linked protein food additive. See MPEP 2144.06. Furthermore, the lupin protein of PERRIER would provide an added nutritive value to copending '635 and produce a more desirable product. It would be obvious to substitute the milk protein of '635 with the lupin protein of the

instant application because it would provide access to a new market of consumers for which the milk protein would be unacceptable (e. g. vegans). Examiner notes the comprising language of the instant application invites additional ingredients.

This is a provisional obviousness-type double patenting rejection.

**Response to Arguments:**

Applicant's arguments filed 11/27/2009 have been fully considered but they are not persuasive.

Applicant's argument that Perrier simply does not disclose or suggest a formulation of a fat-soluble active ingredient in powder form, is not convincing because the copending claims of '635 recite --stable powderous formulations--, coextensive with the preamble of the instantly rejected claims. And the only limitation of the instantly claimed invention that copending 10/564,635 cannot provide is the lupin protein.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's argument against claims 12, 16 and 17 (specifically for the claimed use of the transglutaminase cross-linking enzyme) is confusing because claims 12, 16 and 17 were not included in the obvious-type double patenting rejection presented in the final rejection dated 07/22/2009:

1. Claims 1, 6-9, 11 and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 12-14, 16 and 17 of copending Application No. 10/564,635 (hereafter referred to as '635) in view of Perrier et al. (US 5,912,016).

Applicant's argument that:

At bottom, there is simply no teaching, suggestion or motivation in Perrier for making a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked, including with a reducing sugar.

is not convincing because every limitation emphasized is recited in copending 10/564,635, claim 1:

1. (previously presented) Stable powderous formulations comprising a fat-soluble active ingredient in a matrix of a milk protein composition, wherein the protein is thermally cross-linked with a reducing sugar or a reducing sugar derivative selected from a desoxy sugar or an amino sugar.

### ***Conclusion***

The following prior art is made of record and not relied upon is considered pertinent to applicant's disclosure. The following U.S. Patent documents are made of record for applicant's consideration: GROLLIER (US 4,892,727); PERRIER (US 6,132,750); and the following foreign Patent documents are made of record for applicant's consideration: Chyi-Cheng (EP 1,106,174 A1); and FITCHETT (WO 1999/51106).

The following non-patent literature documents are not relied upon but made of record because they are considered pertinent to applicant's disclosure: SCHÄFER (Journal of Agricultural and Food Chemistry, 2005, Vol. 53, pp. 2830-2837); SINGH (Trends in Food Science & Technology, 1991, vol. 2, pp. 196-200); MOTOKI (Trends in Food Science & Technology, 1998, vol. 9, pp. 204-210); WHITEHURST ("Enzymes in Food Technology," CRC PRESS, 2002, pp. 109-143), DOXASTAKIS (Novel Macromolecules in Food Systems, 2000, pp. 7-38); and LQARI (Food Chemistry, 2002, Vol. 76, pp. 349-356).

Claims 1-5, 7-9 and 11-23 have been examined on the merits. Claims 7 and 21 are rejected under 35 U.S.C. 112, first paragraph; claims 2-4 are rejected under 35 U.S.C. 112, second paragraph; claims 1-5, 7-9 and 11-23 are rejected under 35 USC § 103(a); and claims 1, 7-9, 11 and 13 are provisionally rejected on the grounds of nonstatutory double patenting over copending Application No. 10/564,635. No claims allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Thursday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/  
Supervisory Patent Examiner, Art Unit 1619

IVAN GREENE  
Examiner, Art Unit 1619